DETAILED ACTION

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Skerpon on 4/27/2009.

Amend the claims as follows:

1. (Currently amended) A method of detecting the presence of potential contaminating mycoplasma in a test sample not known to contain mycoplasma comprising:

(i) providing ~~a~~ the test sample;

(ii) detecting and/or measuring the activity of an enzyme selected from the group consisting of acetate kinase, carbamate kinase, and a mixture thereof in the test sample, and said activity being indicative of the presence of potential contaminating mycoplasma; and

(iii) identifying the test sample as potentially contaminated with mycoplasma on the basis of detection and/or measurement of said activity in step (ii).

2. (Currently amended) The method of claim 1 further comprising the following steps performed after step (ii) but before step (iii):

(iia) obtaining enzyme activity information of an enzyme selected from the group consisting of acetate kinase, carbamate kinase and a mixture thereof, detected and/or measured in a corresponding control sample; and

(iib) comparing the activity detected and/or measured in the test sample in step (ii) of claim 1 with the activity detected and/or measured in the control sample in step (iia); wherein the test sample is identified as potentially contaminated with mycoplasma in step (iii) if the activity detected and/or measured in the test sample in step (ii) is greater than the activity detected and/or measured in the control sample in step (iia), that is, the ratio of the activity detected and/or

measured in the test sample in step (ii) to the activity detected and/or measured in the control sample in step (iia) is greater than one.

32. (Currently amended) A process for treating a cell culture to remove potential mycoplasma contamination comprising: treating a potentially mycoplasma contaminated cell culture with an agent to remove and/or destroy mycoplasma; and subsequently testing a sample from the culture for potential mycoplasma contamination using the method of claim 1 or 2; if necessary, repeating the process of treating one or more times until mycoplasma contamination is not detected in a sample.

33. (Currently amended) A method of detecting the presence of potential mycoplasma in a test sample not known to contain mycoplasma, comprising the following steps:

(i) providing ~~a~~ the test sample;

(ii) without adding an exogenous reagent (e.g. substrates for kinase activity) to convert ADP to ATP, detecting or measuring ATP in the test sample using a bioluminescent reaction to obtain an ATP and/or light output measurement;

(iii) obtaining an ATP and/or light output measurement from a corresponding control sample;

(iv) determining the ATP and/or light output measurement ratio as (ATP and/or light output measurement from the corresponding control sample)/(ATP and/or light measurement from the test sample); and

(v) identifying the test sample as potentially contaminated with mycoplasma in the event that the ratio of (ATP and/or light output measurement from the corresponding control sample)/(ATP and/or light measurement from the test sample) is greater than one.

49. (Currently amended A method of detecting the presence of potential contaminating mycoplasma in a test sample not known to contain mycoplasma comprising:

(i) providing ~~a~~ the test sample;

(ii) treating the test sample under a condition sufficient to lyse potential contaminating mycoplasma but insufficient to lyse bacterial cells;

(iii) detecting and/or measuring the activity of an enzyme selected from the group consisting of acetate kinase, carbamate kinase, and a mixtur thereof in the test sample, and said activity being indicative of the presence of potential contaminating mycoplasma; and

(iv) identifying the test sample as potentially contaminated with mycoplasma on the basis of detection and/or measurement of said activity in step (iii).

50. (Currently amended) A method of detecting the presence of potential mycoplasma in a test sample not known to contain mycoplasma, comprising the following steps:

(i) providing ~~a~~ the test sample;

(ii) treating the test sample under a condition sufficient to lyse potential contaminating mycoplasma but insufficient to lyse bacterial cells

(iii) without adding an exogenous reagent (e.g. substrates for kinase activity) to convert ADP to ATP, detecting or measuring ATP in the test sample using a bioluminescent reaction to obtain an ATP and/or light output measurement;

(iv) obtaining an ATP and/or light output measurement from a corresponding control sample;

(v) determining the ATP and/or light output measurement ratio as (ATP and/or light output measurement from the corresponding control sample)/(ATP and/or light measurement from the test sample); and

(vi) identifying the test sample as potentially contaminated with mycoplasma in the event that the ratio of (ATP and/or light output measurement from the corresponding control sample)/(ATP and/or light measurement from the test sample) is greater than one.

51. (Currently amended) A method of detecting the presence of potential contaminating mycoplasma in a test sample not known to contain mycoplasma comprising:

(i) providing ~~a~~ the test sample;

(ii) passing the test sample through a filter which retains bacterial cells;

(iii) detecting and/or measuring the activity of an enzyme selected from the group consisting of acetate kinase, carbamate kinase, and a mixtur thereof in the test sample, and said activity being indicative of the presence of potential contaminating mycoplasma; and

(iv) identifying the test sample as potentially contaminated with mycoplasma on the basis of the detection and/or measurement of said activity in step (iii).

52. (Currently amended) The method of claim 51, further comprising the following steps performed after step (iii) but before step (iv):

(iiia) obtaining enzyme activity information of an enzyme selected from the group consisting of acetate kinase, carbamate kinase and a mixture thereof; detected and/or measured in a corresponding control sample; and

(iiib) comparing the activity detected and/or measured in the test sample in step

(iii) of claim 51 with the activity detected and/or measured in the control sample in step (iiia);

wherein the test sample is identified as potentially contaminated with mycoplasma in step (iv) if the activity detected and/or measured in the test sample in step (iii) of claim 1 with the activity detected and/or measured in the control sample in step (iiia),, that is, the ration of the activity detected and/or measured in the test sample in step (iii) to the activity detected and/or measured in the control sample in step (iiia) is greater than one

54. (Currently amended) A method of detecting the potential presense of mycoplasma in a test sample not known to contain mycoplasma comprising the following steps:

(i) providing ~~a~~ the test sample;

(ii) passing the test sample through a filter which retains bacterial cells;

(iii) without adding an exogenous reagent (e.g. substrates for kinase activity) to convert ADP to ATP, detecting or measuring ATP in the test sample using a bioluminescent reaction to obtain an ATP and/or light output measurement;

(iv) obtaining an ATP and/or light output measurement from a corresponding control sample;

(v) comparing the ATP and/or light output measurement ration as (ATP and/or light output measurement from the corresponding control sample)/(ATP and/or light measurement from the tests sample); and

(vi) identifying the test sample as potentially contaminated with mycoplasma in the vent that the ratio of (ATP and/or light output measurement from the corresponding control sample) / (ATP and/or light measurement from the test sample) is greater than one.

Claims Allowance

Claims 1-34, 44-54 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571) 272-0925.

B Shen
Art Unit 1657

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657